

**PATENT****REMARKS**

Claims 1 and 3-21 are currently pending in this application. Claim 2 has been canceled. Claims 1, 3-14, 17 and 21 have been amended. No new matter has been added by these amendments. Applicants have carefully reviewed the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

**Specification Objections**

The specification was objected to for including various underlined or bold-font subject headings, and for including some typographical errors. In view of the "Amendments to the Specification" presented above, Applicants believe the objections to the specification have been overcome.

**Claim Rejections Under 35 U.S.C. §102**

Claims 1-3, 5, 7 10-16 and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,381,493 (Stradler et al.).

Stadler et al. discloses a system that detects ischemia by monitoring changes in ST segments based on samples taken from portions of the cardiac cycle including a sample from the QRS complex, a plurality of samples from the ST segment and an isoelectric-point sample, which is preferably between the P wave and the R wave. See column 17, line 63 through column 18, line 3 and figures 4 and 5. More specifically, Stradler et al. detects cardiac ischemia based on an ST change parameter which is defined as the difference between the mean of the ST segment samples and the isoelectric-point sample. See column 22, lines 1-3, column 25, lines 14-16 and column 26, line 15. The ischemia parameter is compared to a threshold value to determine if ischemia has been detected. See column 26, lines 16-29.

Independent claims 1 and 21 relate to methods and systems for detecting ischemia based on T-wave energy values and T-wave maximum slopes. For example, claim 1 recites detecting a plurality of individual T-waves within cardiac signals;

**PATENT**

determining an energy value and a maximum slope for each of the plurality of individual T-waves; and detecting cardiac ischemia based on the energy values and the maximum slopes.

Applicants submit that Stradler et al. fails to disclose the inventions of claims 1 and 21 because Stradler et al. detects ischemia based on an ST change parameter (defined as the difference between the mean of the ST segment samples and the isoelectric-point sample), not T-wave energy values and T-wave maximum slopes. Regarding the claimed "maximum slopes," in support of the rejection of canceled claim 2 (which related to maximum slopes), the ST change parameter of Stradler et al. was purported to be the same as the claimed "maximum slope." Applicants disagree. As stated above, the ST change parameter is the difference between the mean of the ST segment samples and the isoelectric-point sample. This "difference" is not a maximum slope of a T-wave.

In view of the foregoing, Applicants submits that Stradler et al. fails to teach the invention claimed in independent claims 1 and 21. Accordingly, Applicants request reconsideration of the §102 rejections of these claims and their respective dependent claims.

Regarding dependent claims 11 and 13, Stradler et al. does not disclose determining a running average of normalized energy values of all sinus or paced T-waves. Column 6, line 45 of Stradler et al. (cited by the Examiner in rejecting claims 11 and 13) discloses normalization of the differences between ST segment samples and the isoelectric-point sample. This “normalization” does not involve T-waves, nor does it involve a running average, as recited in claims 11 and 13. Furthermore, Stradler et al. does not disclose calculating a difference between a current T-wave energy value and the sinus or paced T-wave running average; and determining whether the difference exceeds a predetermined sinus or paced beat threshold, as also recited in claims 11 and 13. Column 23, line 10 of Stradler et al. (cited by the Examiner in rejecting claim 11) discloses a noise detection process based on various waveform parameters, including the ST change parameter. This noise detection process, however, is a

**PATENT**

precursor to the ischemia detection process and it not part of the actual ischemia detection process. More specifically, this noise detection process is performed to determine if the data (e.g., ST segment samples, isoelectric-point sample) for a given cardiac cycle will be used for determining ischemia. See column 23, lines 4-5. In view of the foregoing, Applicants believe the portions of Stradler et al. relied upon in rejecting claims 11 and 13 are not relevant to the claimed ischemia detection processes.

Claim 17 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,148,812 (Verrier et al.).

Claim 17 recites a T-wave detection subsystem operative to detect a plurality of individual T-waves in a cardiac signal; a T-wave energy integration subsystem operative to detect a total energy for each of a plurality of the individual T-waves; and a cardiac ischemia detection subsystem operative to detect cardiac ischemia based on the total energy of one of the individual T-waves, an average of the total energies of a plurality of the other T-waves and a threshold value.

Verrier et al. discloses a system for monitoring alternations in T-waves. To this end, each of a series of successive T-waves is partitioned into "B" time divisions, each time division consisting of one or more digital samples. The area of each time division is computed by summing the areas of the one or more samples within the time division. The result is a series of "area" values for each time division. The series of computed areas for each time division is processed to determine T-wave amplitude alternations. See column 6, lines 42-59.

In support of the rejection of claim 17, the Examiner notes that the "B" in Verrier et al. can be a single sample; thus making the energy integration, a "total energy" integration. Applicants find the Examiner's suggestion that "B" may be a single sample confusing and contrary to the teachings of Verrier et al. Specifically, Verrier et al. teaches partitioning the T-wave into a "B" time divisions, where "B" itself may include a single sample or a plurality of samples. If B is one, as proposed by the Examiner, then the T-wave would include only one time division and would not be partitioned. Alternatively, if the Examiner means that each of the "B" time divisions may include only

**PATENT**

one sample, then the area computed based on the one sample would be only for one of the time divisions and not for the entire T-wave. In either case it is significant to note that Verrier et al. does not teach the summation of all samples of all time divisions to obtain a total energy for a T-wave.

In view of the foregoing, Applicants submit that Verrier et al. fails to teach the invention claimed in independent claims 17. Accordingly, Applicants request reconsideration of the §102 rejections of this claim and its dependent claims.

**Claim Rejections Under 35 U.S.C. §103**

Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. in view of U.S. Patent Publication 2002/015807 (Goldin). Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. in view of Verrier et al. Claims 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Verrier et al. in view of Stradler et al.

In view of the foregoing analysis of independent claims 1 and 17 in view of Stradler et al. and Verrier et al. Applicants believe that the rejections under §103 are rendered moot as each of dependent claims 4, 6, 8, 9 and 18-20 depend from allowable independent claims.

Regarding claim 9, Verrier et al. is cited for teaching a method comprising summing individual samples of a digitized T-wave signal to compute total energy. As explained above under the §102 rejection of claim 17, Applicants submit that Verrier et al. does not teach the summation of all samples of all time divisions to obtain a total energy for a T-wave. Accordingly, Applicants request reconsideration of the §103 rejection of claim 9.

